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| 09/254,152      | 02/26/1999  | KENICHI HIGASHIYAMA  | 001560-344          | 6530             |

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RONALD L GRUDZIECKI  
BURNS DOANE SWECKER & MATHIS  
PO BOX 1404  
ALEXANDRIA, VA 223131404

EXAMINER

WANG, SHENGJUN

ART UNIT PAPER NUMBER

1617

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/254,152

Applicant(s)

HIGASHIYAMA ET AL.

Examiner

Shengjun Wang

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 09 December 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 69-86 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 69-86 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Notice of Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
- Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☒ Interview Summary (PTO-413)
- Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114 was filed in this application after appeal to the Board of Patent Appeals and Interferences, but prior to a decision on the appeal. Since this application is eligible for continued examination under 37 CFR 1.114 and the fee set forth in 37 CFR 1.17(e) has been timely paid, the appeal has been withdrawn pursuant to 37 CFR 1.114 and prosecution in this application has been reopened pursuant to 37 CFR 1.114. Applicant's submission filed on December 9, 2003 has been entered.

#### *Double Patenting Rejections*

1. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

2. Claims 69-71, 73, 74, 78-85 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 3 and 4 of U.S. Patent No. 6,117,905. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claimed subject matters in '905 is essentially the same as claimed herein, except claims of '905 have a narrower scope with respect to the amount of 24, 25-methylenecholest-5-en-3b-ol, and have broad scope with respect to the amount of arachidonic acid (30-50% herein vs. more than 20% in '905). Note the 24, 25-methylenecholest-5-en-3b-ol

compositional ratio therein is less than 30% (0.15% of 24, 25-methylenecholest-5-en-3 $\beta$ -ol vs 0.6% of total unsaponifiable).

***Claim Rejection 35 USC - 102***

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 69-71, 73, 74, 76-85 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Shinmen et al. and Shimizu et al.

Shinmen et al. teach a process for production of an unsaturated fatty acid-containing oil comprising culturing with aeration a microorganism belonging to the genus *Mortierella* subgenus *Mortierella* in a liquid medium containing a nitrogen source and collecting the unsaturated fatty acid-containing oil from the cultured product. See, particularly, the summary on page 11 and page 15, the left column. The nitrogen source can be a defatted soybean product, e.g., soybean meal. See, particularly, page 14, left column, the second paragraph. The unsaturated fatty acid-containing oil contains about 18-60 % of arachidonic acid. See, particularly, Fig 3 on page 15. Shinmen et al. do not disclose 24,25-methylenecholest-5-en-3 $\beta$ -ol compositional ratio or the proportion of 24,25-methylenecholest-5-en-3 $\beta$ -ol, or compositional ratio with respect to desmosterol composition ratio. However, Shimizu et al. teach that an unsaturated fatty acid-containing oil obtained from a process similar to the process of Shinmen et al. has a 24,25-methylenecholest-5-en-3 $\beta$ -ol compositional ratio of 21 % and 24,25-methylenecholest-5-en-3 $\beta$ -ol compositional ratio in a proportion of 0.37 with respect to

desmosterol composition ratio. See, page 482, table 1. Therefore, properties such as having a 24,25-methylenecholest-5-en-3 $\beta$ -ol compositional ratio of 35 % or less and 24,25-methylenecholest-5-en-3 $\beta$ -ol compositional ratio in a proportion of 1.2 or less with respect to desmosterol composition ratio are considered inherent properties of the unsaturated fatty acid-containing oil of Shinmen et al.

***Claim Rejection 35 USC – 103***

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 69-86 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shinmen et al in view of both of Shimizu et al and Barclay.

Shinmen et al. teach a process for production of an unsaturated fatty acid-containing oil comprising culturing with aeration a microorganism belonging to the genus *Mortierella* subgenus *Mortierella* in a liquid medium containing a nitrogen source and collecting the unsaturated fatty acid-containing oil from the cultured product. See, particularly, the summary on page 11 and page 15, the left column. The nitrogen source can be a defatted soybean product, e.g., soybean meal. See, particularly, page 14, left column, the second paragraph. The unsaturated fatty acid-containing oil contains about 18-60 % of arachidonic acid. See, particularly, Fig 3 on page 15. Shinmen et al. do not disclose 24,25-methylenecholest-5-en-3 $\beta$ -ol compositional ratio or the proportion of 24,25-methylenecholest-5-en-3 $\beta$ -ol, or compositional ratio with respect to desmosterol composition ratio. However, Shimizu et al. teach that an

unsaturated fatty acid-containing oil obtained from a process similar to the process of Shinmen et al. has a 24,25-methylenecholest-5-en-3 $\beta$ -ol compositional ratio of 21 % and 24,25-methylenecholest-5-en-3 $\beta$ -ol compositional ratio in a proportion of 0.37 with respect to desmosterol composition ratio. See, page 482, table 1. Therefore, properties such as having a 24,25-methylenecholest-5-en-3 $\beta$ -ol compositional ratio of 35 % or less and 24,25-methylenecholest-5-en-3 $\beta$ -ol compositional ratio in a proportion of 1.2 or less with respect to desmosterol composition ratio are considered inherent properties of the unsaturated fatty acid-containing oil of Shinmen et al. Further, Shinmen also teach the nutritive effect of arachidonic acid. See, particularly, the introduction on page 11.

Shinmen et al. does not teach expressly the employment of soybean as the nitrogen source, or the employment of such oil in food products including baby food and animal food.

However, Barclay teaches the employment of arachidonic acid containing oil obtained from culturing microorganism *Mortierella* for food product including baby food and animal food. See, particularly, column 7, line 48-60.

Therefore, it would have been *prima facie* obvious to a person of ordinary skill in the art, at the time the claimed the invention was made, to employ soybean as nitrogen source in the production of the oil and employ the oil food product including baby food and animal food. A person of ordinary skill in the art would have been motivated to employ soybean as nitrogen source in the production of the oil and employ the oil food product including baby food and animal food because soybean is of the few nitrogen source disclosed to be suitable for the fermentation, and the arachidonic acid containing oil is known to be useful in food product including baby food and animal food. The employment of soybean as nitrogen source herein is

seen to be a selection from amongst equally suitable material and as such obvious. Ex parte Winters 11 USPQ 2<sup>nd</sup> 1387 (at 1388).

***Response to the Arguments***

Applicants' amendments and arguments, and the declaration under 35 U.S.C.1.132 have been fully considered, but are essentially moot in view of the new ground of rejections set forth above.

As discussed above, prima facie cases have been established. Regarding the establishment of unexpected results, a few notable principles are well settled. It is applicant's burden to explain any proffered data and establish how any results therein should be taken to be unexpected and significant. See MPEP 716.02 (b). The claims must be commensurate in the scope with any evidence of unexpected results. See MPEP 716.02 (d). Further, A DECLARATION UNDER 37 CFR 1.1323 must compare the claimed subject matter with the closest prior art in order to be effective to rebut a prima facie case of obviousness. See, MPEP 716.02 (e).

Applicants assert that the edible oil claimed herein "have a very low ratio of 24,25-methylenecholest-5-3n-3beta-ol to desmosterol." However, the claimed 35% is not seems very low compared with what disclosed by prior art.

***Allowable subject Matters***

Following subject matters would be allowable if terminal disclaimer is filed to overcome the double patenting rejections.

A method of producing an arachidonic acid containing edible oil comprises culturing a producer microorganism in a fermentor with aeration in the presence of a nitrogen source,

Art Unit: 1617

wherein the nitrogen source is soybean product, and wherein the microorganism is selected from a group consisting of *Mortierella alphina* ATCC 32221 and *Mortierella alphina* ATCC 42430.

The edible oil produced by culturing a producer microorganism in a fermentor with aeration in the presence of a nitrogen source, wherein the nitrogen source is soybean product, and wherein the microorganism is selected from a group consisting of *Mortierella alphina* ATCC 32221 and *Mortierella alphina* ATCC 42430, wherein the oil having a 24,25-methylenecholest-5-en-3 $\beta$ -ol compositional ratio of about 5 %.

The subject matters, based on examples 3 in the specification, are allowable because the employment of soybean as nitrogen source provide unexpected benefit, i.e., very low amount of 24,25-methylenecholest-5-en-3 $\beta$ -ol in the oil.

Note the subject matters disclosed in examples 1,2 and 4 are not patentable distinct from the prior art. Particularly, the amount of 24,25-methylenecholest-5-en-3 $\beta$ -ol in the oil is not very low compared to the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shengjun Wang, Ph.D. whose telephone number is (571)272-0632. The examiner can normally be reached on Monday-Friday from 8:30 to 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (571)272-0629. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9302.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

S. ✓

SHENGJUN WANG  
PRIMARY EXAMINER

3/15/04